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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/450,609

11/30/1999

HELLE WEIBEL

5739.200-US

7926

23650

7590

05/04/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/450,609

Applicant(s)

WEIBEL ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/3/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,9,11-13,16 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,9,11-13,16 and 28 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The response filed February 03, 2005 have been received and entered into the application.

Action Summary

The rejection of claims 6, 7, 9, 11, 12, 13, 16, and 28 under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097) is being maintained for the reasons stated in the previous office Action.

The objection of Claims 29-31 is maintained for the reasons stated in the pervious office Action.

Response to Arguments

Applicants' arguments filed February 3, 2005 have been fully considered but they are not persuasive. Applicants argue that Applicants have compared compositions of the present claims with the compositions suggested by Lohray et al and the data show that improved stability can be obtained for compositions comprising 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione or

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pharmaceutically acceptable salts thereof, and low-water content lactose, microcrystalline cellulose and/or talc. This is not persuasive because the comparison data has been carefully considered but Applicants are reminded that when relying on comparative testing, the applicants are under a duty to compare his claimed invention with the closest prior art. It is noted that Lohray teaches a pharmaceutical composition containing applicants' active agent in tablet, capsule or powder form in combination with pharmaceutically acceptable excipient set forth in claim 6 and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such composition and Applicants' comparing Lohrey's tablet that are not the closest prior since they do not show how the microcrystalline cellulose compare to cellulose in general and anhydrous lactose vs. hydrous lactose gives better stability to the claimed formulation since other variables within the compared formulations differ and thus, it does not appear that applicants have compared the claimed method and composition with that of the closest prior art. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of 12/31/2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 9, 11, 12, 13, 16, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097).

Lohray et al. teaches at page 35, example, applicants' composition in a tablet form. Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent in tablet, capsule, or powder form, in combination with the pharmaceutically acceptable excipient set forth in claim 6, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions. Lohray et al. teach that the above composition typically contains from 1 to 20% by weight of active compound, and the remainder of the composition being pharmaceutically acceptable carrier, diluents or solvents. (page 35, lines 1-3).

Lohray et al. do not expressly teach the low water content comprising anhydrous lactose and specific cellulose set forth in claim 6 and proportions of excipients set forth in claim 9.

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It would have been obvious to one of ordinary skill in the art to modify Lohray composition to employ any form of lactose (e.g. anhydrous lactose) because Lohray et al. teach the composition comprising lactose in general. One would have been motivated to employ any form of lactose as taught by Lohray to provide a pharmaceutical composition containing the active agent for the effective treatment of diabetics because lactose as utilized in Lohray composition encompasses any lactose form including anhydrous lactose as claimed by the Applicants. The proportions of active agents to be used set forth in claim 9 and specified cellulose set forth in claim 6 are deemed obvious because it is within the knowledge of the skilled pharmacologist to optimize the range of amounts of active agents and the excipients to be utilized. Moreover, Lohray et al. teach the ranges of 1-20% as being an active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would optimize this range of excipients within the range of about 20-80% as taught by Lohray et al. Further, Lohray et al. utilize one of cellulose derivative (e.g. carboxymethyl cellulose) as useful excipient and have a viable utility as an excipient which is so closely related to microcrystalline cellulose utilized claimed by the Applicants and it is to be chemically obvious therefrom (cellulose derivatives) in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related chemically would have the same or essentially the same properties.

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
April 22, 2005